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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,312

09/01/2006

Douglas Paul Newton

1-28324

8155

4859

7590

08/21/2008

MACMILLAN SOBANSKI & TODD, LLC  
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TOLEDO, OH 43604-1619

EXAMINER

STOUT, MICHAEL C

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,312	<b>Applicant(s)</b> NEWTON, DOUGLAS PAUL	
	<b>Examiner</b> MICHAEL C. STOUT	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: “characterized in that” should be replaced with “wherein”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Coanda (US 3,345,980).

Coanda discloses a measurement device, capable of measuring a peak flow, comprising a hollow body having an inlet and outlet, (body 4 has an upper opening covered by a cap 5, having a port 8 and an outlet located on the bottom portion of section 3), the cross sectional area of the body being greater than the cross sectional area of the outlet, device is capable of being positioned upright to measure flow, the hollow body

having at least two portions having different cross sectional areas, see Figure 2,  
wherein the cross sectional area increases step-wise, see Figure 2.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-5, 10, 14, 16, 17 18, 19, 21, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie in view of Coanda (US 3,345,980).

Regarding **claim 1**, Currie discloses a flow measurement device comprising

comprising a hollow body [body of the cup 10 defined by the sidewall 14] having an inlet [open end 12] for receiving fluid and an outlet [port 18], wherein the inlet and outlet are spaced apart from each other [see Figure 2], the cross-sectional area of the body being greater than the cross-sectional area of the outlet (the cross-sectional area of the outlet shown in Figure 2 is smaller than the body) and wherein in use the device is oriented such that the inlet is above the outlet and the measured peak flow is proportional to the maximum height of fluid within the body (urine enters the opening of the cup and drains through the port, the level of the urine in the cup will continue to increase until the rate of the stream entering the cup is equal to or less than the rate of the urine exiting the cup, Column 4, Lines 17-40), characterized in that the hollow body comprises at least two portions each having different cross sectional areas Currie further discloses a device wherein the hollow body comprises at least two portions each having different cross sectional areas (the cross sectional area of the hollow body decreases from one end to the other and results in two portions of the hollow body having different cross sectional areas, see Figure 2 and Column 5 Lines 43-59), and where while the design of cup 10 shown in FIGS. 2 and 3 resembles that of an ordinary cup, any design can be used provided the following variables are considered: the size of the exit port and its relation to the possible fluid levels within the cup; the volume of the cup; the placement of the indicia on the cup; the relation between the indicia on the cup and the volume of the cup; and the ability for the indicia to be viewed from a position above the opening of the cup.

Coanda teaches a urometer wherein a hollow body has a cross-section area which increases stepwise (Figure 2).

Both Currie and Coanda teach urine devices.

Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Currie by substituting the gradual sloping increase in Currie with the step-wise means taught by Coanda because both methods of increase the diameter of a container where known in the art at the time of the invention to obtain a different urine cup design.

Regarding **claim 2**, Currie further discloses the device wherein the outlet is circular in cross-section (port 18, Figure 2).

Regarding **claim 3**, Currie further discloses the device wherein the outlet is so shaped and dimensioned as to present a hydro-dynamically thin orifice to fluid efflux (the port 18 is precisely sized so that there is appropriate flow rate of urine exiting the cup 10 and the size of the port 18 can be designed to take into account a range of factors, such as age, bladder size, sex, etc, of the patient, see Column 4, Lines 8-16).

Regarding **claims 4 and 5**, Currie discloses the device further comprising scale means comprising at least one indicia (to enable the user to determine flow rates, the sidewall 14 of the cup 10 contains visual indicia 20, see Column 4, Lines 28-48) for determining the peak height of fluid in the hollow body.

Regarding **claim 10**, Currie further discloses the device wherein the hollow body is constructed from a transparent material (indicia 20 may be provided on the outside of the cup 10 if it is of clear plastic, Column 4, Lines 32-35).

Regarding **claim 12**, Currie further discloses the device wherein the hollow body is cylindrical in shape (wall of the hollow body defines a surface that is cylindrical in shape Figure 2).

Regarding **claim 16**, Currie/Coanda teaches a device wherein the cross-sectional area increases (Figure 2) wherein the scale means for determining the peak height of the fluid comprises the increase in cross-sectional area of said hollow body (the scale means comprises the increase in cross-section area which is used to determine the volume of the cup at that level with visible indicia, see Column 4, Lines 49-65, and Coanda teaches the step-wise increase corresponding to a given amount of fluid with including indica).

Regarding **claims 17 and 23**, Currie/Coanda further teaches the device wherein each step-wise increase in the cross-sectional area of the hollow body includes a step and wherein at least one or (plurality of teeth) are incorporated into the rim of each step. (Coanda teaches a step wise increase comprising at least one indicator, see Figure 2, Currie teaches a plurality of indicators comprising protrusions around the inner/outer surface of the container, for indicating a fluid level, the protrusions shown in Currie figure 2. Furthermore, the specific shape of the indicator, a pyramidal spike is an obvious matter of design choice one of ordinary skill in the art, insofar as the indicator is configured to perform the desired function (i.e. be visible), the specific shape of the indicator is not significant.

Regarding **claim 18**, Currie further discloses a device wherein the fluid is urine (Column 2, Lines 60-63).

Regarding **claim 19**, Currie further discloses a device wherein urine is collected and effluxed through a port, it is inherent that the effluxed fluid would be collected in a container, urine receptacle or toilet.

Regarding **claim 21**, Currie/Coanda discloses determining the peak flow rate of a fluid using the device as claimed in claim 1, comprising the steps of

- (a) introducing fluid to the inlet of the device (a stream of urine is directed through the open end, see Column 4 Lines 17-25); and
- (b) determining the peak fluid level within the hollow body (the fluid will continue to rise until the flow rate equals or drops below the fluid rate through the port); wherein the peak fluid flow rate is proportional to the maximum height of fluid in the body (Column 3, Line 44 through Column 5, Line 2).

Regarding **claim 22**, Currie/Coanda teaches the device wherein each step-wise increase in the cross-sectional area of the hollow body includes a step, and wherein each step extends perpendicularly relative to a wall of the hollow body (as shown in Figure 2 of Coanda the step-wise increase includes a step the ramped section which extends both perpendicularly away from the wall of the hollow body, 3).

Regarding **claim 13**, Currie discloses a device comprising a hollow body having a diameter of about 70-50mm and an outlet orifice having a diameter of about 4mm.

Currie fails to disclose the device wherein the hollow body has a diameter of 30mm and the outlet orifice has a diameter of 4mm.

However it would have been obvious to a person of ordinary skill in the art to modify the device disclosed by Currie by changing the hollow body to create a kit



wherein the hollow body has a diameter of 30mm and an outlet orifice of 4mm in order to change the volume of the hollow body and thereby supply a user with a kit containing a variety of different cups, either having different volumes, exit port diameters, or levels of indicia 20, an individual can self-determine a good or poor urinary stream, or monitor whether his flow rate is increasing or decreasing over a period of time (see Column 5, Lines 59-65).

5. Claims 6, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie/Coanda in view of Muller et al. (US 4,753, 249).

Currie teaches device comprising multiple scale means comprising multiple indicia on the wall of the hollow body for representing a different peak flow rate or range of peak flow rates.

Currie fails to teach a device wherein the scale means comprises a least two different colored bars, or wherein the scale means comprises heat sensitive material providing a semi-permanent or permanent indication of fluid height wherein the heat sensitive material is applied to the wall of the hollow body.

Muller teaches a flow rate detection device comprising a least two different colored bars (84a-84e, liquid crystal ink stripes which change color from translucent to opaque black (Column 7, Lines 23-54), which are made of heat sensitive material to provide a semi-permanent or permanent indication of fluid height (the portions of the

liquid crystal ink coating 36 opening up due to heat from urine Column 5, Lines 35-61), wherein the heat sensitive material is applied to a wall of a hollow body (see Figure 5).

Both Currie and Muller teach flow rate measurement devices.

Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Currie to substitute the heat sensitive color changing bars as taught by Muller for the indicia because color changing indicators of fluid levels are well known in the art (see Muller Column 1, Line 35 through Column 2, Line 17)

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Currie/Coanda in view of Muller as applied to claim 8 above and in further view of Brennan (US 4,776,485).

Currie/Muller fails to teach the device wherein the heat sensitive material is applied to a portion of the wall of the hollow body with a reduce wall thickness.

Brennan teaches the use of a thinner material to facilitate the transfer of heat (Column 6, Lines 9-33)

Currie/Muller and Brennan teach heat transfer.

At the time of the invention it would have been notoriously obvious to a person of ordinary skill in the art to modify the device taught by Currie/Muller by applying the heat sensitive material to a portion wall of the hollow body with a reduced wall thickness in order to facilitate heat transfer from the urine to heat sensitive material as evidenced by Brennan and improve sensitivity of the material to heat, this is because the less amount

of thermal mass between the heat sensitive material and the heat source (urine) will result in less energy being loss to the wall of the hollow body.

7. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie/Coanda in view of Dye et al. (US 3,871,230).

Regarding **claim 11**, Currie discloses a device wherein the body is constructed in a funnel shape which provides the equivalent structure of a funnel connected to the body. Currie fails to disclose a device wherein the inlet is connectable to a funnel.

Dye teaches a flow rate detection device wherein the inlet is connectable to a funnel (the aperture 40 to removeably receive the lower opening portion of 42 of the funnel-shaped member 34, see Column 2, Lines 67 through 14).

Both Currie and Dye teach flow rate detection devices.

Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Currie to include a connectable funnel as taught by Dye in order to help facilitate fluid collection during use and minimize the risk of failing to collect all the urine, because funnels are well known in the art as a means for aiding in collecting fluids.

Regarding **claim 19**, Currie discloses a device for detecting flow rate. Currie fails to disclose the device further comprising a receptacle for catching effluxed fluid.

Dye teaches a device comprising a receptacle (container 24) for catching effluxed fluid.

Both Currie and Dye teach flow measuring devices.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify device disclosed by Currie to include a receptacle for catching effluxed as taught by Dye in order to collect the discharged liquid and determine the volume of the liquid discharged (see Muller Column 6, Lines 33-54).

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Response to Arguments***

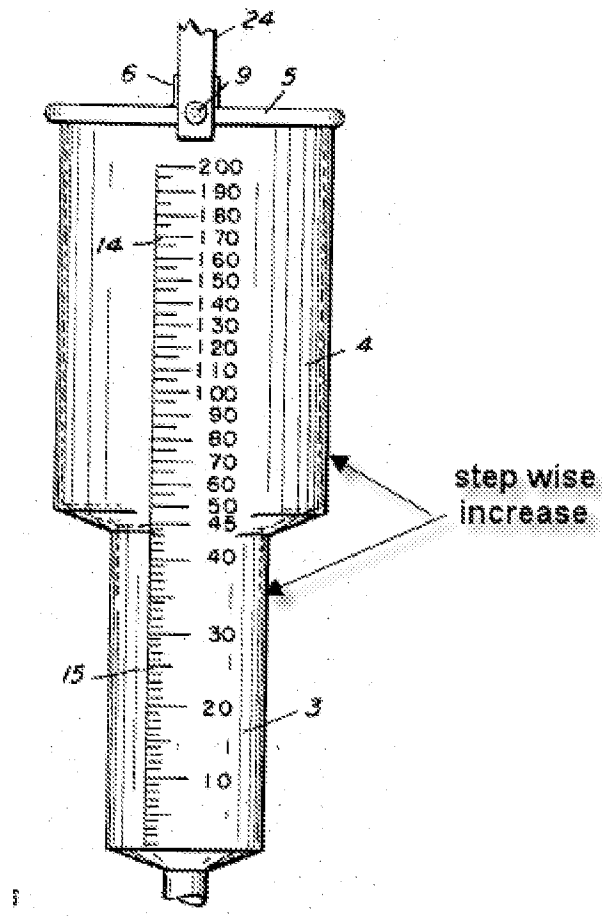
The Applicant's amendment(s), see Claims, filed 5/22/2008, with respect to the Objections to claims 8 and 17 overcome the previous objections. The previous objections of claims 8 and 17 have been withdrawn.

Applicant's arguments filed 5/22/2008 have been fully considered but they are not persuasive.

The applicant argues Coanda and Currie are non-analogous art.

The Examiner Disagrees. Currie, Coanda and the Applicants invention are directed toward urine devices.

The Applicant argues Conanda fails to teach a stepwise increase. The Examiner Disagrees. Conanda teaches a urine fluid container comprising a step-wise increase between the lower portion 3 and the upper portion 4, which is sufficient to meet the limitation as set forth in the claim language, furthermore the rim or edges of the step are connected by a ramped portion where the step shown in Figure 2 comprising a sloped surface which helps facilitate the visualization of the rising fluid, and enlarges the step portion providing a functional equivalent of the pyramidal tooth.



The Applicant's arguments with respect to claims 17, 22, and 23 are directed to newly presented claim language and are addressed in the office action above.

#### ***Contact Info***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is

(571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736